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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,081	02/27/2004	Thomas Ellinger	MAIWAL 3.9-002 CONT	8803

530 7590 03/30/2006

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,081

Applicant(s)

ELLINGER ET AL.

Examiner

Robert T. Crow

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25 and 52-58, drawn to probe arrays, classified in class 435, subclass 283.1.
- II. Claim 26, drawn to a method of array production, classified in class 435, subclass 287.1.
- III. Claims 27-35, drawn to in situ synthesis of an array, classified in class 435, subclass 91.1.
- IV. Claims 36-41, drawn to quality control methods, classified in class 427, subclass 2.11.
- V. Claims 42-51, drawn to methods for detection of target molecules, classified in class 435, subclass 6.
- VI. Claims 59 and 60, drawn to methods of production of monomer building blocks, classified in class 536, subclass 27.22.
- VII. Claim 61, drawn to a nucleoside composition, classified in class 536, subclass 22.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the probe arrays of Invention I can be made attaching restriction fragments of genomic DNA to a substrate.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the probe array of Invention I can be made attaching restriction fragments of genomic DNA to a substrate.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the probe array of Invention I can be used to identify antibodies that bind to nucleic acid sequences.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the probe array of Invention I can be used to identify antibodies that bind to nucleic acid sequences.

Inventions I and VI are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention I operates by hybridizing target molecules to surface immobilized probes and functions to detect said target molecules. In contrast, Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks.

Inventions I and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention I operates by hybridizing target molecules to surface immobilized probes and functions to detect said target molecules. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Inventions II and III are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation. Invention II operates by synthesizing probe molecules followed by immobilization. In contrast, Invention III operates by activating an array surface and synthesizing probe molecules in situ at the site of immobilization.

Inventions II and IV are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention II operates by synthesizing probe molecules followed by immobilization and functions to synthesize a probe array. In contrast, Invention IV operates by detecting the signal intensity of probe molecules and functions to test the quality of the array.

Inventions II and V are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention II operates by synthesizing probe molecules followed by immobilization and functions to synthesize a probe array. In contrast, Invention V operates by incubating the array with a sample to be analyzed and detecting labeled probe fragments and functions to assay for molecular interactions.

Inventions II and VI are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention II operates by synthesizing probe molecules followed by immobilization and functions to synthesize a probe array. In contrast, Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks.

Inventions II and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention II operates by synthesizing probe molecules followed by immobilization and functions to synthesize a probe array. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Inventions III and IV are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention III operates by activating an array surface

and synthesizing probe molecules in situ at the site of immobilization and functions to synthesize a probe array. In contrast, Invention IV operates by detecting the signal intensity of probe molecules and functions to test the quality of the array.

Inventions III and V are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention III operates by activating an array surface and synthesizing probe molecules in situ at the site of immobilization and functions to synthesize a probe array. In contrast, Invention V operates by incubating the array with a sample to be analyzed and detecting labeled probe fragments and functions to assay for molecular interactions.

Inventions III and VI are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention III operates by activating an array surface and synthesizing probe molecules in situ at the site of immobilization and functions to synthesize a probe array. In contrast, Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks.

Inventions III and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention III operates by activating an array surface and synthesizing probe molecules in situ at the site of immobilization and functions to synthesize a probe array. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Inventions IV and V are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention IV operates by detecting the signal intensity of probe molecules and functions to test the quality of the array. In contrast, Invention V operates by incubating the array with a sample to be analyzed and detecting labeled probe fragments and functions to assay for molecular interactions.

Inventions IV and VI are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention IV operates by detecting the signal

intensity of probe molecules and functions to test the quality of the array. In contrast, Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks.

Inventions IV and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention IV operates by detecting the signal intensity of probe molecules and functions to test the quality of the array. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Inventions V and VI are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention V operates by incubating the array with a sample to be analyzed and detecting labeled probe fragments and functions to assay for molecular interactions. In contrast, Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks.

Inventions V and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention V operates by incubating the array with a sample to be analyzed and detecting labeled probe fragments and functions to assay for molecular interactions. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Inventions VI and VII are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different modes of operation and different functions. Invention VI operates by esterification and saponification reactions and functions to synthesize monomer building blocks. In contrast, Invention VII operates as a small molecule and functions as a synthetic precursor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Furthermore, a search for the inventions of all of the groups would not be co-extensive because a search indicating the *process is* novel or nonobvious would not extend to a holding that the *product itself is* novel or nonobvious; similarly, a search indicating that *the product is* known or would have been obvious would not extend to a holding that *the process is* known or would have been obvious.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert T. Crow
Examiner
Art Unit 1634



BJ FORMAN, PH.D.
PRIMARY EXAMINER